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THE MEDICARE & MEDICAID ANTI-KICKBACK STATUTE AND THE SAFE HARBOR REGULATIONS — WHAT'S NEXT?

by Richard P. Kusserow†

THE MEDICARE and Medicaid anti-kickback statute makes it a crime to knowingly and willfully offer, pay, solicit or receive remuneration in exchange for the referral of business covered under Medicare, Medicaid, and other programs. Despite its almost twenty year history, the statute remains controversial. As discussed herein, the statute covers a wide range of conduct in order to serve several important purposes. The health care community has, however, questioned the breadth of the statute and its proper application. The Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) has critical responsibility in enforcing the statute. OIG has attempted to respond to the concerns of the health care community by providing guidance on the implications of the statute through promulgation of the "safe harbor" regulations[1] as well as by other means. This article will discuss the history and purposes of the anti-kickback statute, OIG's efforts to provide guidance on the proper interpretation of this statute, including the "safe harbor" regulations, and enforcement of this statute.

I. BACKGROUND OF THE ANTI-KICKBACK STATUTE

The Social Security Amendments of 1972 established specific penalties for fraud and kickbacks in the Medicare and Medicaid

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1. 56 Fed. Reg. 35,952 (1991).

programs.[2] With regard to Medicare, the statute then provided in relevant part:

> (b) Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any-
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> (1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or
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> (2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services,
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> shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.[3]

A similar provision was enacted which applied to Medicaid.[4] Congress amended the law in 1977, by expanding the prohibited payments to "any remuneration" which was solicited, received, offered or paid "directly or indirectly, overtly or covertly, in cash or in kind."[5] In addition, the previous penalty of a misdemeanor was increased to a felony.[6] In 1980, the statute was amended to require proof of knowing and willful conduct.[7]

In 1987, the Medicare and Medicaid anti-kickback provisions were combined into the present section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b).[8] That section now provides:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind -
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> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under title XVIII or a State health care program, or
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> (B) in return for purchasing, leasing, ordering, or ar-

2. Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b)(Medicare), § 242(c) (Medicaid), 86 Stat. 1419 (1972).

3. This was codified at § 1877 of the Social Security Act, 42 U.S.C. § 1395nn (1972).

4. This was codified at § 1909 of the Social Security Act, 42 U.S.C. § 1396h (1972).

5. Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, § 4 (1977). The identical prohibition appeared at § 1877(b) of the Act with respect to Medicare and at § 1909(b) of the Act with respect to Medicaid. Congress expressly intended to "define the term 'any remuneration' broadly." H.R. Rep. No. 393, 95th Cong., 1st Sess, pt. 1, at 53 (1977) *reprinted in* 1977 U.S.C.A.N. 3056; *see also* S. Rep. No. 453, 95th Cong., 1st Sess. 12 (1977).

6. Pub. L. No. 95-142, § 4, 91 Stat. 1179 (1977).

7. Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2625 (1980).

8. Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), Pub. L. No. 100-93, § 4, 101 Stat. 688 (1987).

> ranging for or recommending, purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under title XVIII or a State health care program,
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> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under title XVIII, or a State health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under title XVIII or a State health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

In addition, in 1987 Congress also made two significant changes to the statute in response to OIG's concerns about providing an alternative remedy to criminal prosecution and providing more guidance to the health care industry. First, Congress provided DHHS an administrative remedy to enforce the statute by excluding violators from the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services Programs.[9] Previously, the only enforcement mechanism had been a criminal remedy, which did not result in many prosecutions because of the effort and resources required to put together a criminal case. The exclusion sanction, in certain cases, can be as significant as a criminal sentence. For example, a hospital cannot be sent to jail, but would suffer severe financial and public relations consequences by being excluded from the programs.

Second, Congress addressed the situation where, because the language of the statute was so broad, providers were uncertain as to what practices were prohibited and what practices were permissible.[10] The consequence of this was that providers were reluctant to engage in many arrangements which were not harmful to the pro-

9. *Id.* at § 2, codified at 42 U.S.C. § 1320a-7(b)(7) (1988). "State health care program" is defined in 42 U.S.C. § 1320a-7(h) (1988).

10. S. Rep. No. 109, 100th Cong., 1st Sess. 27 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 707-08.

grams and beneficiaries, and which may even have been helpful. Congress, therefore, directed the Secretary to promulgate regulations setting forth specific payment arrangements which would be exceptions to the statute and therefore would not be the basis of criminal or administrative prosecution.[11]

In the health care industry, referrals are a potent source of business. Because consumers are less knowledgeable about medical issues, they rely on medical experts for referrals. Thus, there is a tremendous temptation to offer economic incentives to those who can influence the flow of business. Financial incentives to refer create a conflict of interest which can lead to referrals which would not otherwise occur. Furthermore, even when a referral is clearly necessary from a medical point of view, financial incentives to refer can obscure a health care practitioner's goal of referring to the best qualified source. The statute seeks to address these problems and thereby serves four purposes: (1) preventing overutilization of services; (2) containing program costs; (3) preserving patient freedom of choice; and (4) protecting competition.

The first and most important purpose is to minimize the risks of overutilization. The statute presumes that if someone can gain financially by referring business, the person is more likely to do so, even when the item or service is not necessary. In all cases, increased utilization increases costs, and sometimes it exposes our beneficiaries to the health risks of unnecessary medical procedures.

Second, the statute aims at containing costs. In part, it does this by deterring overutilization. However, even if only medically necessary items or services are provided, the statute protects the program against the increased costs of those goods and services. Providers inevitably raise their prices to pass along to consumers and health care programs the amount of the illegal remuneration they pay to obtain referrals.

Third, the statute helps to ensure that patients have freedom of choice among providers, as guaranteed under the Medicare program.[12] Assuming that a beneficiary genuinely needs a particular item, the patient should not be steered to a particular provider for the service because the referrer is paid a referral fee. As consumers, we expect those in a position to safeguard our health to keep our interests uppermost when they refer us to another provider.

Finally, the statute protects competition. When a referral is

11. MMPPPA at § 14(a), codified at 42 U.S.C. § 1320a-7b(b)(3)(D) (1988).
12. 42 U.S.C. § 1395a (1988).

based on a referral fee, the free market is distorted. Competition on the basis of free enterprise values, such as price, quality, and convenience is reduced, making it harder for others to compete for the business.

II. THE "SAFE HARBOR" REGULATIONS

Publication of the safe harbor regulations was the culmination of an almost four year process. To respond to Congress' direction that DHHS consult with the health care community before promulgating regulations,[13] and to educate ourselves on the types of arrangements that existed and would be worthy of protection, OIG first published a notice of intent to develop regulations, seeking comments on the content of safe harbor regulations.[14] The 137 timely comments OIG received assisted us in developing proposed regulations, which were published in January, 1989.[15] OIG received over 750 comments, which were reviewed and considered in the drafting of the final regulations issued on July 29, 1991.[16]

In drafting the safe harbor regulations, OIG attempted to balance two competing concerns. First, we tried to draft the regulations to accommodate as many non-abusive arrangements as possible. Second, we tried to minimize the risks of allowing abusive arrangements within the safe harbor. We believe each of the eleven safe harbors contained in the final rule contains criteria which offer reasonable assurance that abusive activities will not receive the comfort of being in a safe harbor.

Many commentators requested that the regulations spell out generic criteria and that any business arrangement which met these criteria would be protected. For example, it was suggested that OIG protect arrangements that were "cost effective" or were an "accepted business practice." The problem with such criteria is that they are too subjective to provide much guidance to the public on how to structure their business arrangements. Consequently, we opted to set forth as many bright line rules as possible.

The final regulation includes eleven categories of business practices that will be immune from prosecution under the anti-kickback statute. These practices are known as "safe harbors" because they

13. H.R. Rep. No. 85 (II), 100th Cong., 1st Sess. 27 (1987).
14. 52 Fed. Reg. 38,794 (1987).
15. 54 Fed. Reg. 3088 (1989).
16. 56 Fed. Reg. 35,952 (1991).

provide an area where people can act in complete safety from prosecution under the anti-kickback statute.

One area of confusion is the effect of *not* being in a safe harbor. It is not possible to "violate" a safe harbor. The anti-kickback statute itself, not the safe harbors, makes conduct illegal. If one's conduct implicates the anti-kickback statute, then one runs the risk of prosecution unless one is in a safe harbor.

A summary of each "safe harbor" follows. This summary is not designed to substitute for the regulation but, rather, is intended to highlight some of the critical concerns and resolution of those concerns which are reflected in the final rule. In evaluating any situation, one should look to the statute and implementing regulations.

1. *Investment Interests*

The anti-kickback statute prohibits any remuneration in exchange for, or to induce, referrals of Medicare or Medicaid business. Many health care practitioners have investments in health care related business, and they refer their patients to these businesses. A classic example is a general practitioner who owns part of a radiology center, and sends all of his patients needing x-rays to that center. Obviously, the more profitable the center is, the more money the physician will make. The profit distribution the physician receives from his ownership in the center can be a payment which induces the referral of Medicare and Medicaid business. Thus, profit distributions from such an investment can violate the anti-kickback statute.

OIG recognizes that there are many sound reasons why those involved in health care would seek an investment in the same industry. For example, it is a natural inclination to invest in a business in an area where one has familiarity. A physician may refer to his radiology center because he is familiar with the radiologists and administration and is confident that the center will provide good services. In addition, there is nothing inherently wrong in seeking an investment with good profit potential. The problem, however, is that such investments raise the very concerns that are behind the anti-kickback statute: that a physician may make a decision concerning the referral of a patient which is influenced by his own financial interests. OIG sought to balance these concerns by drafting safe harbors for investment interests that would permit health care practitioners to earn profits from investments in health care businesses, but only if their financial incentive to refer was significantly diluted.

The investment interest safe harbor has two parts — one aimed at investments in large, publicly traded companies, and one for investments in smaller entities. OIG drafted a safe harbor that essentially protects profit distributions from large companies on the theory that a shareholder's dividends do not increase based on that shareholder's referrals, so that the dividend distribution will not have the effect of influencing a referral.[17]

With regard to smaller businesses, we designed a safe harbor that is intended to protect profit distributions from businesses that can survive on their own merits rather than simply on the business referred from interested investors, and where the distributions are only minimally related to referral patterns. The regulation sets forth a number of standards which must be met to qualify for this safe harbor, including that no more than 40 percent of the investments in each class of investments may be held by investors who are in a position to make or influence referrals, furnish items or services or otherwise generate business for the entity; no more than 40 percent of the revenues can be generated from referrals from interested investors; and a passive investor cannot be required to generate business.[18] Through these and other standards included in the regulation, OIG attempted to create room for those in the health care industry to have the opportunity to invest in health care business while minimizing the concerns that motivated the passage of the anti-kickback statute.

2. *Space Rental*

One of the most traditional schemes for paying kickbacks is to disguise the payments as rental payments for space. For example, a physician may refer patients to a company that provides mobile diagnostic services. The company may rent space from the physician to store supplies or equipment. The question, however, is whether the value of the space being rented relates to the rental payment. For example, a company which rents a closet from the physician for $1000/month, or for $100 per hour of use, may be compensating the physician for referrals via these "rental" payments.

Obviously, in many cases a health care practitioner is legitimately renting space and we have published a safe harbor that is designed to protect legitimate rental arrangements. The safe harbor includes several standards, the most significant of which is that the

17. 56 Fed. Reg. at 35,984 (1991).
18. 56 Fed. Reg. at 39,584-85 (1991).

payments must be consistent with fair market value.[19] The regulation defines fair market value as the value of the property for general commercial purposes, excluding the value that any party would attribute to the property because of its proximity to sourses of referrals.[20] For example, a physical therapist may rent space near a physician from that physician believing that the physician will refer many patients to the therapist because of the close proximity of the offices. Nonetheless, the property must be rented at a rate that reflects its normal commercial value to anyone. This is not a pure economic evaluation of fair market value, which would likely increase the value of the space to the therapist because of its proximity to a referral source. But the regulation defines fair market value in this way to eliminate the factor which is the concern behind the anti-kickback statute — payment for referral of business. The safe harbor also requires the agreement to set forth certain information and be for at least a one year term[21] to minimize the risk that the contract will be repeatedly modified so as to compensate for changing referral patterns.

3. *Equipment Rental*

Rental of equipment poses many of the same concerns as rental of space. The critical question to be evaluated is whether the rent charged is in exchange for the equipment, or does it also include payment for referrals? For example, assume a hospital owns a CT scan which it rents to a radiologist. The hospital is in the position to influence its staff physicians to refer patients to that radiologist. The anti-kickback statute prohibits the hospital from receiving payment for influencing or arranging for referrals, and it precludes the radiologist from paying for referrals. Arguably any rental payment from the radiologist to the hospital exceeding the fair market value could be seen as compensating the hospital, at least in part, for referrals.

In order to protect legitimate receipt of rents from equipment, there is a safe harbor for equipment rental which includes standards similar to the safe harbor for space rental requiring that the rent must be consistent with fair market value and not be based on the quantity or value of referrals.[22] Fair market value is again defined as excluding any value which would otherwise be placed on the

19. 56 Fed. Reg. at 35,985 (1991).
20. *Id.*
21. *Id.*
22. *Id.*

equipment because of its proximity to sources of referrals.[23] The regulation also includes standards which restrict the parties' ability to modify the contract to account for referrals.[24]

4. *Personal Services and Management Contracts*

OIG has encountered many situations where an entity that depends on referrals, for example, a laboratory, contracts with a referral source, such as a physician. Often the physician is required to perform legitimate services, such as analyzing test results. The question OIG confronts is whether the payments to the referral source are for the services provided or for the referrals. If the payments for the services are significantly higher than the fair market value of the services provided, this raises the issue of why there is a high payment - unless the payment is intended to compensate for referrals.[25] Any payment for services which are provided by someone who is in a position to refer could arguably be viewed as payment for, among other things, referrals. OIG wanted to protect legitimate payments for services, but not protect payment for referrals. Thus, we designed a safe harbor which has, among its other standards, the requirement that the payment be consistent with the fair market value of the services provided and not take into account the volume or value of any referrals.[26]

5. *Sale of Practice*

It has become common for hospitals to buy a physician's ongoing practice. The obvious purpose of such a purchase is to buy a stream of patients who will continue using the practice and may also be referred to the hospital for further work.[27] This guarantees a stream of referrals for the hospital, which we believe can lead to higher program costs and to decisions being made based on finan-

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23. *Id.*

24. *Id.*

25. *See United States v. Lipkis*, 770 F.2d 1447, 1449 (9th Cir. 1985) (Mobile Medical Industries (MMI) referred lab work to Automated Laboratory Services (ALS) in exchange for 20 percent kickback. "To account for the kickback payments, MMI provided ALS with certain services. . . . The fair market value of these services was substantially less than the compensation MMI received from ALS, and there is no question that ALS was paying for the referrals as well as the described services.")

26. 56 Fed. Reg. at 35,985 (1991).

27. *See e.g.*, Linda Perry, *Advisory Group to Hospitals: Snap Up Physicians Practices*, MODERN HEALTHCARE, Feb. 4, 1991, at 40 (Health Care Advisory Board recommends that hospitals purchase physician practices because they can control where patients are sent for inpatient procedures and can control the operating expenses physicians incur to care for their patients).

cial incentives rather than the patients' best interests. OIG therefore limited safe harbor protection to only those situations where a *practitioner* buys an ongoing practice of a physician who is retiring or who for other reasons will not be in a continuous position to make referrals.[28] The safe harbor is limited not because OIG intends to prosecute every other situation involving the sale of a practice, but because of the difficulty of structuring a broader safe harbor which would not include purchases where the payments are intended to compensate the practitioner for his ongoing role in making referrals.

6. *Referral Services*

A referral service is a source through which persons in need of care can obtain the name(s) of physicians or other providers. Many practitioners depend on such services for patients. Obviously, payments to referral services by practitioners are payments for referrals. Nonetheless, such services can be useful to consumers.

Safe harbor referral services must meet certain requirements, the two most critical of which are that any payment to the referral service by the physician or other participant are based only on the costs of operating the referral service rather than the volume or value of referrals or business generated for the referral service and that the referral service disclose to the prospective patient various information concerning the relationship between the physician and the referral service.[29] The first requirement addresses the concern that a referral service cannot be paid for the value of referrals. The disclosure requirement ensures that prospective patients will learn what makes the physician or other practitioner qualified to participate in the service. For example, if a hospital operates a service which is open only to its staff physicians, it is important for a beneficiary to know whether physicians are required to have any qualifications beyond being a staff member, and that physicians who are not included in the referral service may still be qualified. Notably, this is the only safe harbor that includes a disclosure requirement. Because a patient has no special relationship with a referral service, OIG felt disclosure would serve a useful function by enabling a patient to assess the basis for the referral.[30]

28. 56 Fed. Reg. at 35,985 (1991).

29. 56 Fed. Reg. at 35,985-86 (1991).

30. In other cases, we opted against requiring disclosure because we believe the special relationship between a patient and his or her health care provider may act to undermine the desired effect of disclosure: making a patient critically assess the referral. If a physician dis-

7. *Warranties*

Warranties on equipment may implicate the anti-kickback statute because the manufacturer is using the warranty to induce a consumer to purchase that equipment. Warranties do, however, benefit the public by ensuring that the manufacturer maintains ongoing responsibility for the product, thereby giving the manufacturer an incentive to produce quality goods.

Thus, the regulations protect payments made pursuant to warranties as long as they meet certain criteria. OIG has incorporated reporting requirements similar to those in the Discount Safe Harbor discussed *infra* to give the programs information which ultimately may be used in making coverage and reimbursement decisions.[31] In addition, the regulations protect competitive replacement agreements where the agreement honors the initial warranty and does not provide additional incentives.[32] OIG believes that if a patient needs to replace, for example, a defective pacemaker, he should be able to choose a different product when another manufacturer is willing to meet the terms of the original manufacturer's warranty.

8. *Discounts*

This safe harbor implements the statutory exception for discounts, which states that the statute does not apply to:

> a discount or other reduction in price obtained by a provider of services or other entity under Title XVIII or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under Title XVIII or a State health care program.[33]

The safe harbor defines what OIG believes Congress meant by "discount."[34] We determined that Congress intended only to protect reductions in price of the same good or service. We do not believe Congress intended to protect so-called "bundled purchase arrangements," where different goods or services are sold together. Often, such arrangements involve the sale of some good at full price while others are substantially reduced in price or given away for free.

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closes a financial interest in a medical services company, a patient may just as easily conclude that the company is superior as that the referral requires further scrutiny because of the physician's financial interest.

31. *Id.* at 35,986.

32. *Id.*

33. 42 U.S.C. § 1320a-7b(b)(3)(A) (1988).

34. 56 Fed. Reg. at 35,987 (1991).

Because the person who offers or gives a discount is not the same person who must "appropriately reflect" the discount in claims for program payment, the safe harbor differentiates various reporting obligations of sellers and buyers. If the seller complies with its obligations, the seller is insulated from criminal prosecution and exclusion, regardless of what the buyer does. In addition, reporting requirements vary, depending on the type of entity involved and method of reimbursement.

The most common question OIG is asked is whether the safe harbor protects *all* the discounts or other reductions in price that Congress intended to protect when it enacted the discount exception. We believe it does. Congress sought to except discounts or other reductions in price from the reach of the statute to the extent that they were "properly disclosed" and "appropriately reflected" in the costs claimed or charges made to the programs. We believe the safe harbor conforms with Congress's intent to exempt discounts to the extent that they are passed along to the programs in a manner consistent with the vagaries of different reimbursement methods.

9. *Employees*

The anti-kickback statute also excepts from prosecution:

> any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.[35]

In implementing this exception, the safe harbor regulations adopt the definition of "employee" found in the Internal Revenue Code at 26 U.S.C. § 3121(d)(2), which defines employee as any individual who would be considered an employee under the usual common law rules applicable in determining the existence of an employer-employee relationship.[36] This safe harbor does not protect payments to independent contractors. Protection for independent contractors is not justified by the legislative history.[37] Moreover, independent contractors are generally not under as close a degree of supervision as employees, and therefore may be more likely to engage in abusive conduct. Consequently, in order to receive protection, payments to independent contractors would have

35. 42 U.S.C. § 1320a-7b(b)(3)(B) (1988).

36. 56 Fed. Reg. at 35,987 (1991).

37. *See* 56 Fed. Reg. at 35,981 (1991) (discussing that Congress passed an exception which was expressly limited to bona fide employment relationships).

to meet the requirements of another safe harbor, such as the one for personal services contracts.

10. *Group Purchasing Organizations*

The third statutory exception to the anti-kickback statute applies to:

> any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under the XVIII or a State health care program if -
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> (i) the person has a written contract with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and
>
> (ii) in the case of an entity that is a provider of services (as defined in 42 U.S.C. § 1395x(u)), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity.[38]

The safe harbor regulations implement this provision by defining group purchase organization (GPO) and by reflecting Congress' concern that GPO fees that exceed three percent are abusive.[39] Thus, we protect only those situations where the fee to the GPO is three percent or less of the purchase price of the goods and services or where the agreement specifies the maximum amount the GPO will be paid by each vendor.[40]

11. *Waiver of Medicare Coinsurance and Deductible In Certain Cases*

This safe harbor implements the fourth statutory exception, which permits

> a waiver of any coinsurance under Part B of the Title XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Services Act.[41]

The safe harbor also permits the waiver of coinsurance and deductible by a hospital who is paid by the prospective payment system, as long as the hospital meets certain standards, including not

38. 42 U.S.C. § 1320a-7b(b)(3)(C) (1988).
39. *See* H.R. Conf. Rep. 1012, 99th Cong., 2d Sess. 310-11 (1986).
40. 56 Fed. Reg. at 35,987 (1991).
41. 42 U.S.C. § 1320a-7b(b)(3)(D) (1988).

claiming the amount waived as bad debt and thereby shifting the burden to the Medicare program.[42] We have concluded that the demand for inpatient services is basically inelastic and waiver will not induce a beneficiary to undergo an inpatient procedure. Moreover, since hospitals are paid a predetermined amount per diagnosis under the prospective payment methodology, the actual charges to the beneficiary will not affect how much Medicare must pay.

In other contexts, however, particularly under Medicare Part B, we view routine waiver of coinsurance and deductible as a serious violation of the anti-kickback statute, as reflected in a recent OIG Special Fraud Alert.[43]

In summary, complying with a safe harbor guarantees that conduct which would otherwise violate the anti-kickback statute will be immune from prosecution.

III. ADDITIONAL GUIDANCE

The safe harbor regulations are a significant step toward alleviating concerns about the proper interpretation of the anti-kickback statute. They give the health care community specific guideposts by which to tailor conduct, and thereby avoid prosecution for a kickback violation. The preamble to the regulations provides further guidance by identifying certain practices that OIG believes may be abusive and which are, therefore, potential subjects for

42. 56 Fed. Reg. at 35,987 (1991).

43. *See* OFFICE OF INSPECTOR GENERAL, DEP'T. OF HEALTH & HUM. SERVS., SPECIAL FRAUD ALERT: ROUTINE WAIVER OF COPAYMENTS OR DEDUCTIBLES UNDER MEDICARE PART B (1991). Medicare beneficiaries are generally required to pay an annual deductible and then a certain copayment for each item or service covered by Medicare (typically 20 percent). As the OIG's Fraud Alert explains, requiring Medicare beneficiaries to share in the costs of items and services is very important because it causes people to be better health care consumers, and select items or services because they are medically necessary, rather than simply because they are free. Unfortunately, we have found that many providers inappropriately waive these fees as a marketing technique to get beneficiaries to order items or services because they are free (*i.e.*, the beneficiary has no out-of-pocket expense) rather than because they are needed. Ultimately, Medicare ends up paying for unnecessary items or services. Routine waiver may violate the anti-kickback statute, because providers are unlawfully inducing beneficiaries to obtain services from them. In addition, when providers routinely waive copayments or deductibles, they may be submitting false claims to the government. If a provider claims its charge for a service is $100, but routinely waives the copayment, the actual charge is $80. Medicare should be paying 80 percent of $80 (or $64) rather than 80 percent of $100 (or $80).

One important exception to the above rule is that providers can waive the copayment or deductible for particular patients based on their financial hardship. The point, however, is that a provider must make this determination of hardship on an *individualized* basis, rather than automatically waiving these fees for all patients as a marketing technique.

prosecution.[44]

In addition to the safe harbors, however, OIG is taking measures to assist the public in evaluating whether conduct violates the anti-kickback statute. First, OIG intends to issue additional safe harbors in the future. We see this as an evolving process: we will use comments received from the public and our knowledge of the health care industry to continually reassess the appropriateness of existing safe harbors and the need for new safe harbors. This will enable the industry to continue to develop efficient and innovative arrangements that increase quality and cost-effectiveness of health care but do not abuse the Federal health care programs.

Second, we intend to continue to issue Fraud Alerts. In contrast to the safe harbor regulations, which specify conduct immune from prosecution, the Fraud Alerts highlight areas where OIG has particular concerns because of the impact of certain practices on the health care programs.[45] On occasion, OIG also issues reports on areas which OIG has studied and concluded that kickback problems exist.[46]

Third, OIG plans on issuing "interpretive rules" to clarify ambiguities in a particular safe harbor or a conflict between two or more safe harbors. These rules will not address whether a specific fact situation falls within a safe harbor, but rather, will explain terms or resolve other questions of more general applicability.

Fourth, as discussed in the next section, OIG will continue to prosecute violations of the statute. The administrative and judicial decisions which will result from these prosecutions will assist the health care community by providing guidance from administrative adjudicators and the courts on the type of conduct which violates the statute, and the standards that will be used in evaluating that conduct. A large step was recently taken in this regard with the recent decision of the DHHS Departmental Appeals Board

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44. *See, e.g.*, 56 Fed. Reg. at 35,963 (1991) (regulations do not protect free gifts to beneficiaries); 56 Fed. Reg. at 35,975 (1991) (regulations do not protect sale of physician practices that extend beyond one year).

45. *See, e.g.*, OFFICE OF INSPECTOR GENERAL, DEP'T. OF HEALTH & HUM. SERVS., SPECIAL FRAUD ALERT: ROUTINE WAIVER OF COPAYMENTS OR DEDUCTIBLES UNDER MEDICARE PART B (1991); OFFICE OF INSPECTOR GENERAL, DEP'T. OF HEALTH & HUM. SERVS., SPECIAL FRAUD ALERT: JOINT VENTURE ARRANGEMENTS (1989).

46. *See, e.g.*, FINANCIAL ARRANGEMENTS BETWEEN HOSPITALS AND HOSPITAL-BASED PHYSICIANS, OFFICE OF INSPECTOR GENERAL Pub. No. OIE-09-89-00330 (1991) (discussing possible violations of anti-kickback statute in financial arrangements between hospitals and hospital-based physicians).

(DAB)[47] in *The Inspector General v. The Hanlester Network.*[48]

In the *Hanlester Network* case, OIG alleged that the Hanlester Network established three limited partnership laboratories in California, which were joint ventures owned by various physicians and the Hanlester Network, which served as the general partner. Our position was that the joint ventures were shell entities whose purpose was to refer laboratory business from the physician-investors to SmithKline Beecham Clinical Laboratories, which served as the manager of the laboratories.[49]

OIG alleged *inter alia*, that: physicians invested in these partnerships with little risk and promises of high rates of return; the number of shares that the marketing director offered the physicians sometimes depended on their expected referrals; the partners were expected to refer their laboratory work to the joint venture; Hanlester delegated to SmithKline the right to decide whether to perform the laboratory tests at the partnership labs or to refer them to SmithKline's central reference lab; SmithKline referred about 90 percent of the tests to its own reference labs; the management agreement between SmithKline and the partnership labs provided that the labs would bill Medicare and then pay SmithKline 76 percent of the revenues, thus allowing the partnerships to keep 24 percent for virtually no work performed; and that these revenues were paid to the limited partners primarily for their referrals.

In December 1989, the OIG proposed to exclude ten individuals and entities involved in this case for violations of the anti-kickback statute. After a two week hearing, the administrative law judge (ALJ) issued his decision in the spring of 1991, taking a narrow reading of the anti-kickback statute.[50] The ALJ concluded that payments which had the effect of encouraging referrals were not enough to violate the statute — rather, one needed proof of an agreement to refer as a condition of payment in order to establish a violation.[51] OIG appealed, and the DAB vacated all the findings

47. The DAB is an administrative body within DHHS that hears a variety of cases, including cases where someone challenges an exclusion from the Medicare and State health care programs which OIG has proposed for violating the anti-kickback statute. *See generally* 45 C.F.R. pt. 16.

48. *Hanlester Network*, 1991 Medicare & Medicaid Guide (CCH) ¶ 39,566 (1991).

49. SmithKline settled with the OIG in December 1989 for $1.5 million. In addition, SmithKline agreed to the OIG's understanding of the facts from its investigation, and agreed to terminate or renegotiate contracts found objectionable by the OIG. However, SmithKline disputed that its conduct violated the statute.

50. *Hanlester Network*, 1991 Medicare & Medicaid Guide (CCH) ¶ 39,094 (1991).

51. *Id.* at 25,544.

that the OIG contested in its appeal.[52]

The DAB held that the statute does not require proof of an *agreement* to refer.

> The plain meaning of the statutory language, as well as its context, purpose, and history, support a conclusion that a violation occurs whenever an individual or entity knowingly and willfully offers or pays anything of value, in any manner or form, with the intent of exercising influence over a physician's reason or judgment in an effort to cause the referral of program-related business. Nothing in the statutory language explicitly or implicitly requires an agreement, nor can the legislative history or case law on the anti-kickback statute reasonably be read to require an agreement.[53]

The DAB emphasized that it is necessary to consider all relevant circumstances concerning a transaction or relationship to determine the parties' intent and hence whether the statute was violated.[54] The DAB also rejected the ALJ's position that the statute could not be interpreted broadly because of the wide range of practices it would implicate.[55] The DAB held that it is not appropriate to consider, in determining whether the statute was violated, whether an arrangement is common since Congress intended to alter many common practices.[56] In addition, the DAB noted that "[i]t is not necessary that a payment succeed in inducing a referral for it to have been intended to serve that end."[57]

The DAB pointed out that the term "any remuneration" means "anything of value in any form or manner whatsoever. The direction in which money payments flow in a transaction is not determinative of whether remuneration has been paid."[58] The DAB found that the ALJ's analysis requiring a direct payment to the referral source "clearly frustrates Congressional intent to focus on the substance rather than on the form of the transaction."[59]

The DAB held that the OIG need not prove harm to the Medicare or State health care programs in order for the ALJ to impose an exclusion. Rather, once the OIG demonstrates that a party violated the statute, that party has the burden of proving the absence

52. *Hanlester Network*, 1991 Medicare & Medicaid Guide (CCH) ¶ 39,566 (1991).
53. *Id.* at 27,740.
54. *Id.* at 27,762.
55. *Hanlester Network*, ¶ 39,094 at 25,542-43.
56. *Hanlester Network*, ¶ 39,566 at 27,762-63.
57. *Id.* at 27,755 n.22.
58. *Id.* at 27,764.
59. *Id.* at 27,759.

of harm as a factor to weigh in lessening the length of exclusion.[60]

On March 10, 1992, Administrative Law Judge (ALJ) Steven Kessel issued his decision on remand from the Departmental Appeals Board (DAB) in *The Inspector General v. Hanlester Network*, the first administrative case filed under section 1128(b)(7) of the Social Security Act ("Act"), to redress violations of the Medicare and Medicaid anti-kickback statute (section 1128(b) of the Act). The Respondents in this case established three joint venture clinical laboratories in California, recruited physicians to become limited partners in the ventures, and paid these partner physicians profit distributions in return for their referrals of laboratory business which was reimbursed by Medicare and Medicaid.

Applying standards previously enunciated by the Departmental Appeals Board in this case on September 18, 1991, the ALJ found that: 1) by offering and paying profit distributions to the limited partner physicians, all nine of the Respondents violated section 1128(b)(2) of the Act, which prohibits the knowing and willful offer or payment of remuneration with the intent to induce the referral of program-related business; and 2) by soliciting and receiving remuneration from SmithKline, the contract manager, in return for the referral of laboratory tests, seven of the Respondents violated section 1128(b)(1) of the Act, which prohibits the knowing and willful solicitation or receipt of remuneration in return for the referral of program-related business. Based on these violations, the ALJ permanently excluded the three laboratories from participation in the Medicare and state health care programs, and excluded the Hanlester Network for a period of two years. However, because the ALJ found that no remedial purpose would be served by excluding any of the four individual Respondents in the case, or one corporation that acted as a general partner of Hanlester, he did not impose any exclusions against these parties.

With respect to his decision not to exclude five of the parties, the ALJ ruled that 1) such exclusions, in this particular case, are not required by regulations promulgated on January 29, 1992, governing the Inspector General's sanction and civil monetary penalty authority (*see* 42 C.F.R. §§ 1005.4(c)(5) and (6)); and 2) section 1128(b) does not mandate an exclusion of every individual or entity who has engaged in conduct which authorizes the Secretary to impose and direct an exclusion under section 1128(b). The ALJ found that the record in the case did not contain evidence supporting a

60. *Id.* at 27,764.

finding that any of these Respondents was untrustworthy. This determination was based on the ALJ's finding that at the time these Respondents established the joint venture laboratories, they did not know that they were violating the Medicare and Medicaid anti-kickback statute.

The Inspector General is considering whether to appeal the ALJ's Decision on Remand to the Departmental Appeals Board.

In summary, the DAB's decision in the *Hanlester Network* provides broad and extensive guidelines as to whether conduct violates the anti-kickback statute.

Although OIG is making extensive efforts to continue assisting in the interpretation of the anti-kickback statute, one step we will *not* be taking is issuing rulings in response to questions as to whether specific fact situations satisfy a safe harbor. As discussed in the preamble to the regulations,[61] we will not be issuing "advisory opinions", primarily because it is virtually impossible to accurately assess a situation where an element of a violation is intent. Moreover, such an opinion, even with qualifications and limitations, could be used by parties to unfairly establish a "reasonable doubt" for criminal prosecution, on the theory that they made some effort to determine if their conduct was lawful — even if they left out key elements of the arrangement.

Despite the lack of advisory opinions, the available information on the statute plainly provides enough guidance so that those who wish to structure their practices to completely avoid prosecution may do so. For those who choose to continue operating in a manner that risks prosecution, the next section discusses the enforcement process and the factors OIG considers in determining whether to undertake an anti-kickback case.

IV. THE OIG ENFORCEMENT PROCESS AND PRIORITIES

The anti-kickback statute, as previously discussed, is primarily a criminal statute, but also has an administrative remedy. Thus, the statute has two enforcement tracks.

Generally, the process will start with an allegation brought to OIG's attention that someone is violating the anti-kickback statute. In our experience, these allegations are most frequently made by

61. 56 Fed. Reg. at 35,959-60 (1991).

aggrieved competitors.[62] Allegations are generally referred to one of OIG's ten regional offices (depending on the geographical location of the involved parties). Depending on available resources, an OIG agent will investigate the allegations to determine if they have merit. If the allegations have merit, then the agent will generally present the case to a United States Attorney. The United States Attorney will review the case and evaluate whether we can prove "knowing and willful" intent to violate the statute beyond a reasonable doubt. If, due to the facts, or insufficient resources, the United States Attorney declines the case, OIG will consider whether to pursue the administrative sanction of excluding the alleged violator from the Medicare and Medicaid (and other state health care) programs.[63] OIG assesses whether the case merits administrative sanctions, and whether we can meet our standard of proof: to prove a knowing and willful violation of the statute by a preponderance of the evidence.[64]

If the decision is made to proceed with an exclusion, OIG will then send a letter to the alleged violator stating that OIG proposes to exclude them from Medicare and the State health care programs. The letter gives the alleged violator the opportunity to request an administrative hearing and asks the party to set forth any defenses. The exclusion cannot be imposed until after the alleged violator has an opportunity for a hearing before an ALJ.[65] If the party requests a hearing, the case is sent to one of the ALJs assigned to the DAB. After a process allowing for discovery, which basically is limited to an exchange of documents and rulings on any pretrial motions, a hearing is held. After the hearing, the parties can file post-hearing briefs, and then the ALJ will render a decision. Either party may file exceptions to the ALJ decision, which will be heard by the Appellate Division of the DAB, before a panel of three individuals.[66]

A final decision of the DAB is a final decision of the Secretary. Thus, if the ruling is adverse for OIG, OIG has no further right of

62. To make an allegation, one can contact one of OIG's Regional Offices or call the toll-free hotline, 1-800-368-5779.

63. OIG has no authority to seek a financial penalty for kickback violations.

64. Our burden of proof for the sanction of exclusion is less than it would be in a criminal case. *See* S. Rep. No. 109, 100th Cong., 1st Sess. 10, *reprinted in* 1987 U.S.C.C.A.N. 682, 690 ("It is the Committee's intent that the burden of proof requirements . . . would be those customarily applicable to administrative proceedings.") *Hanlester Network*, Ruling on Respondents' Motion and Request for Ruling, (Civil Remedies Division Docket Nos. C-186-C-192, No. C-208 and C-213) at 2 (1990).

65. *See* 42 U.S.C. § 1320a-7(f).

66. New regulations dealing with procedures for appealing exclusions will soon be promulgated. *See* 55 Fed. Reg. 12,205 (1990) (proposed rules).

appeal. If the ruling is adverse to the other party, that party has a right to appeal to Federal District Court to have the DAB decision reviewed for whether the decision is supported by substantial evidence.[67] This is not a de novo hearing.

In determining whether to pursue a criminal prosecution or an administrative exclusion, the threshold test is deciding whether the case promotes the goals of the OIG:

> to provide leadership and coordination and recommend policies for activities designed (A) to promote economy, efficiency, and effectiveness in the administration of, and (B) to prevent and detect fraud and abuse in, [the programs and operations of DHHS].[68]

Beyond this general standard, there are many additional specific factors that go into determining whether a case is worthy of prosecution. The degree of harm to programs and beneficiaries, the resources available to prosecute, and the strength of the available evidence are just a few of the criteria to be considered. Clearly, OIG must, in any case, assess whether its resources merit a prosecution. But it is important to recognize that one goal of OIG is to deter future wrongdoing. Thus, what some may deem a "small" case, in terms of the impact of the scheme, may well be worth prosecuting because of the deterrent effect such a prosecution will have on similar schemes. That is not to say that OIG intends to prosecute what some people call "technical violations" of the statute: situations which violate the statute but which, as a practical matter, do not have any negative effect or from which nothing significant can be gained by terminating the conduct. The point, however, is that what can be gained from prosecution depends on one's perspective. In OIG's view, Congress passed the anti-kickback statute because of its justifiably serious concern over the consequences that payment for referrals has on the Federal health programs and the health industry in general. It is OIG's responsibility to implement this concern through vigorous enforcement of the statute.

We do not intend to automatically reject for prosecution any case involving past unlawful conduct, merely because the parties now conform their conduct to a safe harbor. It is the statute, not the regulations, which makes conduct illegal; depending on the circumstances involved and the gravity of the violation, such a case may well be worthy of prosecution because of the past conduct. However, to the extent that parties who are in violation of the stat-

67. 42 U.S.C. § 1320a-7(f) (1988); 42 U.S.C. § 405(g) (1988).

68. Inspector General Act of 1978, 5 U.S.C. app. § 2(2).

ute make good faith efforts to change their conduct prospectively to comply with a safe harbor, this factor will be considered in assessing whether a prosecution is appropriate. Similarly, those cases where people do not attempt to conform their arrangement to a safe harbor are especially ripe for prosecution.

In all events, even if a particular arrangement cannot completely comply with a safe harbor, the participants will be at less risk if they make a good faith effort to get close to the safe harbors, and if the aspects of the arrangement which deviate from the safe harbors do not implicate the concerns underlying the anti-kickback statute. Although being close to a safe harbor does not absolutely immunize someone from prosecution, it does suggest an intent to obey the law, and that will be accorded due weight by investigators and prosecutors.

V. CONCLUSION

The past few months have resulted in substantial development of the law under the anti-kickback statute. The final safe harbors and the *Hanlester Network* decision provide a great deal of guidance as to what is illegal. In addition, OIG's Fraud Alerts and the safe harbor regulations indicate the types of practices OIG is concerned about, and the standards that will be used in assessing alleged kickback violations. Because the intent of the parties is a crucial element in determining whether the statute is violated, it is not possible to be more specific than we have been in describing unlawful conduct. It is OIG's hope that health care providers will use this guidance to conform their conduct to the law and thereby engage in healthy business relationships.